

REMARKS

The invention, as claimed in independent claim 1, relates to a blister pack device for a powder inhaler. The device includes a blister pack having a body which includes first and second surfaces which are substantially parallel to each other (e.g., surfaces of elements 11, 12 shown in Fig. 1; p. 8, lines 18-20) and have medicament containing blisters arranged in rows running parallel to a longitudinal axis of the blister pack. The blisters in each row in the first surface are configured to sit between the blisters in a co-operating row in the second surface, as is shown for example in Figs. 3 and 4 (p. 2, lines 6-8; p.9, lines 19-24), which configuration permits a smaller size for the blister pack device. In addition, the blisters in the first and second surfaces are rotationally symmetrically disposed about the longitudinal axis of the blister pack. (p. 1, lines 21-24). This permits the user to first empty (after a number of uses over a period of time) the blisters on the first surface when the blister pack is mounted in a support unit, e.g., unit 1 in Figs. 2, 3 and 4, with the user accessing the blisters through openings 87 in the support unit that are aligned with the blisters. The user can then remove the blister pack, rotate the blister pack 180°, and reinsert it into the support unit (as noted in the application at pages 17 and 18) and then access and eventually empty the blisters on the second surface, which blisters automatically align with the positions that the blisters of the first surface had occupied in the first position (i.e., aligned with the openings 87), owing to the rotational symmetry. Claim 1 recites the support unit that encloses the blister pack and includes a plurality of openings (e.g., 87) in one surface which correspond with the blisters in the first or second surface adjacent thereto regardless of which way the user inserts the blister pack. Claim 1 has been amended to recite into that the blister pack is insertable into the support unit in one of two positions in which either the blisters in the first surface or the blisters in the second surface align with the openings in the support unit. Claim 1 has also been amended to make it clear that the longitudinal axis is parallel to the first and second surfaces, and that the first and second surfaces are spaced from each other.

The claims were rejected under 35 USC 112, second paragraph for failing to explicitly recite that the blister pack was insertable into the support unit. Claim 1 has been amended to now make this explicit, and the claims are submitted to fully comply with 35 USC 112, second paragraph.

In the office action, claim 1 was rejected under 35 USC 103 on the basis of Friberg WO98/00351 in view of Von Schuckmann WO97/40876.

Friberg discloses a blister pack with first and second surfaces that fold over so that the blisters on one surface sit between blisters on another surface. The office action refers to Figs. 1e and 2d as showing the blisters in one surface sitting between blisters in the other surface. Friberg describes a blister of the pack as holding "one piece of medicine, e.g. a tablet or capsule" (page 3, line 35) and describes breaking the lid foil with a user's finger (page 7, lines 10-13). The blister pack is supported on internal supporting unit 30 having a respective opening for each blister in both surfaces and is covered by protective unit 20. Friberg does not disclose or in any way suggest using the blister pack on any type of inhaler device, let alone one having a support unit that receives the blister pack in one of two positions in which either the blisters in the first surface or the blisters in the second surface align with the openings in the support unit.

In the office action it was stated that Friberg "does not disclose the support element having a plurality of openings in one surface which corresponds with the blisters in the first OR second surface adjacent thereto regardless of which way the user inserts the blister pack, But Von Schuckman discloses such. (See figs 1-4, 17-27 and supporting text)."

Von Schuckmann describes a support unit that receives a blister pack with blisters on the blister pack being aligned with the openings in the support unit. The blister pack has all blisters in a single surface and is insertable in only one position, unless, perhaps, one views different parts of the same surface as "two surfaces," and assumes that two positions can result by rotating the blister pack about an axis that is perpendicular to the surface. The blister pack in Von Schuckmann does not have two surfaces that are spaced from each other and is not insertable in

one of two positions in which either the blisters in the first surface or the blisters in the second surface align with the openings in the support unit.

It would not have been obvious to use Friberg's blister pack in Von Schuckman's device, and, even if one did, it would not result in the invention as claimed. Friberg's blister pack is not designed to be used with any kind of inhaler device. If one were to insert Friberg's blister pack in Von Schuckman, it most likely would be in the unfolded single-surface position shown, e.g., in Fig. 1a in Friberg, as such a single-surface arrangement is described in VonSchuckman and that is the arrangement in which Friberg's blisters are accessible. One skilled in the art would not use Friberg's orientation of Figs. 1e and 2d, because this is different than the orientation of VonSchuckman, and, in this orientation, the blisters of Friberg are protected by protective unit 20 and not accessible. Friberg does not describe using the folded orientation without protective unit 20.

The prior art, taken alone or in combination, also does not suggest in any way a blister pack with spaced surfaces and staggered blisters that is insertable in one of two positions in a support unit which either the blisters in the first surface or the blisters in the second surface align with the openings in the support unit, as required by claim 1.

The subject matter of claim 1 accordingly is not rendered obvious by Friberg and Von Schuckmann, and claim 1 is allowable under 35 USC 103(a).

The remaining claims depend on claim 1 and are allowable with it over the prior art.

Claims 8-14, 17 and 18 have also been rejected for obviousness-type double patenting over claims 1-53 of U.S. Patent No. 6,410,712 in view of Friberg WO 98/00351.

U.S. Patent No. 6,410,712 corresponds to Von Schuckmann WO97/40876. Claims 1-53 recite various aspects of the inhaler including a substantially planar surface with a series of depressions (i.e., a blister pack with all blisters in a single surface and that is insertable in only one position) and a support unit. The blister pack in claims 1-53 does not have two surfaces that are spaced from each other and is not insertable in one of two positions in which either the

blisters in the first surface or the blisters in the second surface align with the openings in the support unit. Friberg is discussed above.

It would not have been obvious to use Friberg's blister pack in the device of claims 1-53, and, even if one did, it would not result in the invention as claimed. Friberg's blister pack is not designed to be used with any kind of inhaler device. If one were to insert Friberg's blister pack in the device of claims 1-53, it most likely would be in the unfolded single-surface position shown, e.g., in Fig. 1a in Friberg, as such a single-surface arrangement is described in claims 1-53 and that is the arrangement in which Friberg's blisters are accessible. One skilled in the art would not use Friberg's orientation of Figs. 1e and 2d, because this is different than the orientation of claims 1-53, and, in this orientation, the blisters of Friberg are protected by protective unit 20 and not accessible. Friberg does not describe using the folded orientation without protective unit 20.

The prior art, taken alone or in combination, also does not suggest in any way a blister pack with spaced surfaces and staggered blisters that is insertable in one of two positions in a support unit which either the blisters in the first surface or the blisters in the second surface align with the openings in the support unit, as required by claims 8-14, 17 and 18, and the double patenting rejection should be removed.

Accordingly, all claims are submitted to be in condition for allowance, and such allowance is respectfully solicited.

Applicant : Von Schuckmann et al.
Serial No. : 09/646,140
Filed : September 13, 2000
Page : 10 of 10

Attorney's Docket No.: 06275-218001 / D 1920-1P US

Enclosed is a \$950.00 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: Mar 17, 2004

William E. Booth
William E. Booth
Reg. No. 28,933

Fish & Richardson P.C.
225 Franklin Street
Boston, MA 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

20825080.doc